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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/490,622	01/24/2000	Stuart Edwards	STUA0010	7398

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EXAMINER
THISSELL, JEREMY

ART UNIT	PAPER NUMBER
3763	

DATE MAILED: 02/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/490,622

Applicant(s)

EDWARDS, STUART

Examiner

Jeremy T. Thissell

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 December 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) 4,5,7,9-13,15-17,21,22 and 38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 6, 8,14,18-20,23-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 6, 8, 14, 18, 19, 25-32, and 34-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Guglielmi (US 5,916,235) in view of Slepian et al (US 5,674,287).

Guglielmi teaches all the claimed subject matter including shrinkage of enlarged body lumens by using heat. (col. 4, lines 31-32) However, Guglielmi does not teach local heating of an infused fluid (saline). Slepian teaches such heating of saline that is delivered directly from the catheter or through a "leaky balloon," as well as temperature control feedback. Col. 9, lines 53-66; col. 10, line 46; col. 14, line 37. It would have been obvious to use the body lumen heating procedure in Slepian for shrinking an enlarged body lumen, such as taught in Guglielmi, since such a treatment is well-known in the art, as taught by Guglielmi. One of ordinary skill in the art would have found it further obvious that the selected dimension would be the normal dimension of the body lumen, since returning the body to its normal condition/functional capacity is the goal of most medical procedures.

Claims 1, 2, 8, 14, 20, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swartz et al (US 5,938,660) in view of Guglielmi (US 5,916,235).

Swartz teaches all the claimed subject matter including heating a saline solution (col. 11, lines 44-54). However, Swartz does not teach shrinking the lumen down to a selected dimension, more specifically the normal dimension. It would have been obvious to combine Guglielmi with Swartz for the same reasons it would have been obvious to combine Guglielmi with Slepian as discussed above.

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Swartz in view of Guglielmi and further in view of Goffinet (WO 85/02779).

Swartz as modified by Guglielmi teaches all the claimed subject matter except for the tissue being cancerous, engorged, inflamed, or infected. Goffinet teaches ablation (like Swartz) of malignant (cancerous) tumors. (page 1, line 2). It would have been obvious to one of ordinary skill in the art that a tissue to be ablated by Swartz would include cancerous tissue as taught by Goffinet, since ablation of cancerous tissue is well-known in the art, as demonstrated by Goffinet.

Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Guglielmi in view of Slepian and further in view of Gencheff et al (US 5,423,744).

Guglielmi as modified by Slepian teaches all the claimed subject matter except for promoting epithelial growth. Gencheff teaches introduction of a medicinal agent and energy such that it promotes endothelial cell growth. (col. 6, lines 1-3). Endothelial

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cells are a kind of epithelial cells. It would have been obvious to one of ordinary skill in the art that the promotion of endothelial cells, as in Gencheff, is an important part of treatment of body lumens, and that it would be obvious to make it a part of Guglielmi's treatment.

Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Swartz in view of Guglielmi and further in view of Lesh (US 5,971,983).

Swartz as modified by Guglielmi teaches all the claimed subject matter except for pacing. Lesh teaches treatment of the heart using an ablation catheter and a pacing device. It would have been obvious to perform the heart tissue ablation of Swartz and include the pacing device of Lesh, particularly since Swartz is concerned with the muscle stimulating electrical impulses of the heart.

Response to Arguments

The examiner has reversed the Guglielmi and Slepian references. Although, as applicant argued, it may not be obvious to use the Slepian device in the manner of Guglielmi, it would be obvious to use the well-known simple method of heating an infused fluid, as taught by Slepian, to perform the tissue heating method of Guglielmi.

Conclusion

Finality is hereby withdrawn and this action is being made NON-FINAL in view of new grounds of rejection.

Contacts

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeremy T. Thissell whose telephone number is (703) 305-5261. The examiner can normally be reached on 8:30-7:00 Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached at (703) 308-3552. The fax phone numbers for all fax communications is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1148.

jt
February 10, 2004


BRIAN L. CASLER
SUPERVISORY PATENT EXAMINER
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